REMARKS

With entry of this amendment, claims 17-19 and 35-37 are under examination. Claims 1-7, 20 and 31 have been canceled. New claims 35-37 have been added. The specification has been amended at page 14 to correct a translation error. It is submitted that support for the correction is clear from the context of the description in the paragraph. Support for the amended and new claims can be found in the originally filed claims, and throughout the specification. No new matter has been added. Reconsideration is requested.

The Examiner indicated that a certified English translation of the priority document must be filed in order to obtain the benefit of that application. A certified English translation is filed herewith.

Rejection Under 35 USC § 112, First Paragraph

Claims 17-20 and 31 were rejected under 35 USC § 112, first paragraph, because the Examiner believes the specification, while being enabling for a transgenic mouse comprising in its genome a mutated TLR-9 allele such that no functional N-terminal fragment of TLR 9 is produced and wherein peripheral macrophage of said mouse exhibits decreased responsiveness to CpG ODN, does not reasonably provide enablement for any other animal commensurate with the scope of these claims. To the extent to which it may be considered applicable to the presently pending claims, this rejection is traversed for the following reasons.

In order to expedite prosecution, the claims have been amended to be limited to a transgenic mouse. Claims 20 and 31 have been canceled. The claims presently under examination are drawn to a transgenic mouse comprising in its genome a gene encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence is excessively expressed, and a transgenic (knockout) mouse lacking said receptor proteins. An example of means for obtaining such mice are presented in the Examples of the specification (for example, at page 14) and will be familiar to those of skill in the art.

New claim 35 has been added which recites a transgenic mouse with the specific features that the Examiner considered to be supported by the specification. Accordingly, it is

respectfully submitted that claim 35 is free of the rejection. New claim 36 recites a knockout mouse lacking receptor proteins specifically recognizing bacterial DNA having an unmethylated CpG sequence. Support can be found, *inter alia*, at pages 20-21 of the specification. New claim 37 depends from claim 17, and recites that the gene encodes TLR9. Support can be found, *inter alia*, at page 5 of the specification.

It is respectfully submitted that the claims under examination are fully enabled. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 17-20 and 31 were rejected under 35 USC § 112, first paragraph, as failing to satisfy the written description requirement. It is the Examiner's position that the claims embrace gene sequences that are not disclosed or sufficiently described in the application and that the claims embrace a genus of gene sequences of which the inventors were not in possession at the time the application was filed. Claims 20 and 31 have been canceled.

The claims have been amended to be limited to transgenic mice that either lack, or overexpress, receptor proteins specifically recognizing bacterial DNA having an unmethylated CpG sequence, e.g. TLR9, as noted above. It is respectfully submitted that there is ample written description for the presently claimed transgenic mice. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 USC § 112, Second Paragraph

Claims 17-20 and 31 were rejected under 35 USC § 112, second paragraph, as being indefinite. The claims have been amended and are believed to be free of this rejection. The Examiner stated that the term "excessively", as used in claim 17, was not defined in the claim, and that the specification does not provide a standard for ascertaining the requisite degree of expression. Claim 17 has been amended to clarify that expression is compared to that in a wild-type mouse, as would be evident from the specification to those of skill in the art. In claim 18, the examiner indicated that the expression "wherein the function of the gene... is destroyed on a chromosome" was indefinite. Claim 18 has been amended to recite "A knockout mouse lacking a functional gene...", an expression that will be clear to those of skill in the art. Claims 20 and 31 have been canceled. The Examiner's comments concerning the expression "according to" in claims 19-20 and 31 are not understood. In view of the

Examiner's statement that this rejection would be overcome by a more specific reference to animal, and that such amendment has been made, it is believed that this rejection is overcome. For all of the above reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 USC § 102

Claims 17-20 and 31 were rejected under 35 USC § 102(e) as being anticipated by Bauer et al. A certified English translation of the priority document is filed herewith. It is respectfully submitted that this antedates the Bauer et al. reference and overcomes the rejection. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 18-19 and 31 were rejected under 35 USC § 102(b) as being anticipated by Takeuchi et al. Claim 31 has been canceled. To the extent to which this rejection may be applicable to the presently pending claims, it is traversed for the following reasons.

Takeuchi et al. describes differential roles of TLR2 and TLR4 in recognition of gram-negative and gram-positive bacterial cell wall components, and teaches TLR4-deficient and TLR2-deficient mice. TLR2-deficient mice lack a response to peptidoglycan (PGN). TLR4-deficient mice are hyporesponsive to lipopolysaccharide (LPS) and lipoteichoic acid (LTA). Takeuchi et al. do not disclose a knockout mouse lacking a functional gene encoding a receptor protein specifically recognizing bacterial DNA having an unmethylated CpG sequence, as presently claimed in claims 18-19. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 18-19 and 31 were rejected under 35 USC § 102(a) as being anticipated by Hemmi et al. A certified English translation of the priority document is filed herewith. It is respectfully submitted that this antedates the Hemmi et al. reference and overcomes the rejection. Reconsideration and withdrawal of the rejection are respectfully requested.

Nonstatutory Obviousness-Type Double Patenting

Claims 18-19 and 31 were provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending application no. 10/517,663 (" '663 "). Claim 31 has been canceled. It is noted that the allegedly conflicting claims in the copending application have been canceled, and further, that

the claimed transgenic mouse of the '663 application comprises a homozygous inactivation of TLR1, which encodes a polypeptide recognizing triacylated mycobacterial lipoproteins. In contrast, the presently claimed transgenic mice lack or overexpress TRL9, which reacts with bacterial DNA having an unmethylated CpG sequence. Accordingly, it is respectfully submitted that the pending claims in the present application are free of this rejection. Withdrawal of the rejection is respectfully requested.

All rejections having been addressed, it is respectfully submitted that this application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

Date: 1/11/07

Ann S. Hobbs, Ph.D.
Registration No. 36,830
VENABLE LLP
P.O. Box 34385
Washington, D.C. 20043-9998
Telephone: (202) 344-4000
Telefax : (202) 344-8300